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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/068,212

02/06/2002

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3433-338

8926

7590

05/27/2008

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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

05/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/068,212

Applicant(s)

FEARNOT ET AL.

Examiner

CHERYL MILLER

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15, 18-30, 36-38 and 46-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14, 15, 26-29, 36-38, 46-48 and 54-56 is/are allowed.
- 6) ☒ Claim(s) 18-25, 30, 49-53, and 57-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 14-15, 18-30, 36-38, and 46-61 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has argued that Wallace (US 6,669,719 B2) does not disclose a sheet that defines a plurality of extensions and apertures. The examiner disagrees. Wallace has shown in figure 56, a sheet having extensions (plugs) and apertures (174). Both the apertures and extensions are part of the sheet. The extensions extend into and are attached to the sheet, therefore considered part of the sheet.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-25, 30, 49-53, and 57-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 recites the limitation "the collagenous extracellular matrix" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 50 depends upon claim 49 and inherits all problems associated with the claim.

Claim 60 recites the limitation "the submucosal tissue" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 61 depends upon claim 60 and inherits all problems associated with the claim.

Claims 18, 20, 23, and 30 each recite, "the tube formed *with* a sheet". This statement is indefinite. It appears applicant intended to claim, --the tube formed *from* a sheet--, as the tube is formed from a different shape (formed from a sheet), it is not formed with an additional sheet layer (formed with a sheet). Claims 19, 21-22, 24-25, 49-53, 57-59 depend upon the above claims and inherit all problems associated with the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-20, 22, 30, 49-53, and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al. (US 6,669,719 B2, cited previously). Wallace discloses a medical device (see fig.56) comprising a tube (1) having a lumen (seen in fig), formed from a sheet, the sheet having a plurality of extensions (plugs) and apertures (174), the first extension (plug) having a portion (bottom of plug) received through the aperture so as to overlie an underlying layer of material (bottom of plug overlies under layer), wherein the extension portion (plug) is bonded to the underlying layer (plug is made of adhesive so will bond itself to under layer; col.24, lines 52-55), wherein the tube (1) has a plurality of extensions (plugs) and apertures (174). Wallace discloses the medical device substantially as claimed, however does not disclose the tube to be made of collagen submucosa or other biomaterials. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use

submucosa as an alternative to the polymer or alloy of Wallace, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (submucosa being a known material used in the vascular art area due to its biocompatibility and bioremodelability). *In re Leshin*, 125 USPQ 416.

Allowable Subject Matter

Claims 14, 15, 26-29, 36-38, 46-48, and 54-56 are allowed.

Claims 21, 23-25, and 60-61 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738